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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,191	07/11/2003	Karl F. Popp	24948	3528
20529	7590	02/04/2008		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 02/04/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,191

Applicant(s)

POPP, KARL F.

Examiner

Lakshmi S. Channavajjala

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response dated 10-31-07 is acknowledged.

Claims 26-31 are pending in the instant application.

Instant claims 1-25 and 32-37 have been canceled.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-31-07 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al.

Instant claims are directed to a process of preparing the composition comprising forming a benzoyl peroxide intermediate dispersion at 15-25 degrees C having 2.25% to 12.5% benzoyl peroxide with a viscosity of 60,000 to 250,000, forming clindamycin

intermediate solution having 0.5% to 1.5% clindamycin in the final product and mixing the two to yield a mixture having a final pH of 4.5 to 5.0 and wherein the final viscosity of the mixtures is lower than that of benzoyl peroxide and is between 50,000 to 200,000; and the mixture is stable for the treatment period. .

Baroody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66). Baroody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and clindamycin is combined with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Baroody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5. Thus, the pH taught by Baroody encompasses the instant claimed pH. For the claimed stability (claims 7-8), Baroody shows that the composition is stable over a long period of time (table 7 and 8) or even up to 4 months (example 24 in col. 17).

With respect to the viscosity, Baroody discloses that initial viscosity of benzoyl peroxide is in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. Instant claims require that the viscosity of the mixture of benzoyl peroxide and clindamycin is lower than the viscosity of benzoyl peroxide dispersion. Baroody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, the instant claims do not state what the initial and final viscosities are and in addition, recites initial and final viscosities

that overlap with each other, thus allowing for very little difference between the initial and final viscosities. Baroody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Baroody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that need require benzoyl peroxide and clindamycin combination. In this regard applicants have not shown the criticality of the initial and final viscosities as a function of stability of the composition.

Response to Arguments

Applicant's arguments filed 10-30-07 have been fully considered but they are not persuasive.

The Examiner has failed to establish a prima facie case of obviousness against the presently rejected claims. To establish a prima facie case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U. S. (April 30, 2007), "a court must ask whether the improvement is more than the predictable use

of prior art elements according to their established functionsit [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issueit can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does., because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, supra, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In re Wilson, 165 USPQ 494,496 (C.C.P.A. 1970).

It is argued that the Baroody reference does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the claimed process results in a final composition having a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion. Instead, Baroody actively teaches the exact opposite, requiring the final composition to have a viscosity *higher* than the benzoyl peroxide intermediate

composition. This would motivate one skilled in the art who wishes to invent a storage-stable clindamycin topical composition, to avoid taking the opposite relative viscosity between the benzoyl peroxide and the final composition as in the presently pending claims.

Applicants' arguments are not persuasive because as rightly pointed out, in the recent *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. ___, (April 30, 2007), it has been stated that a teaching, suggestion or motivation is required to support a finding of obviousness. The nature of the problem in the instant case as well as the teaching of Baroody is the same, storage and long-term stability of a composition comprising (same components) benzoyl peroxide and clindamycin. Under the TSM test, according to the above ruling, the teaching or suggestion or motivation may be found in the prior art, nature of the problem or the knowledge of one of an ordinary skill in the art. Further, according to *KSR International Co. v. Teleflex Inc. et al.*, "when there is a design need or market pressure to solve a problem and there are a finite number of identified and predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp". In this case, Baroody clearly understands the need to develop a stable benzoyl peroxide composition. Baroody provides the teaching that the composition containing the above active agents are limited by storage stability and also suggests several factors such as pH, viscosity, gelling agent contribute to the stability (col. 3, L 14-36, table 3). In the same section, Baroody describes mixing a suspension of benzoyl peroxide with a solution of clindamycin (which meets the process steps a-c of instant claims) and also

state that the viscosity may be relatively low and high, suggesting that it may be varied. Thus, Baroody is directed to solving the same problem (nature of problem) as that of instant. Accordingly, a skilled artisan would have been able to recognize the viscosity at which the composition retains its stability for a long period of time. In addition, while instant claims recite the initial viscosity in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000, the storage stability of the compositions described in the instant specification is no greater than that of Baroody (teaches stability at room temperature upto 4 months).

Applicants submit that the teachings of the Baroody reference are not such general conditions for the presently pending claims as recited in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), but instead are the opposite conditions teaching away from the presently pending claims. It is argued that the Examiner should not recite *In re Aller* to negate the nonobviousness of the presently pending claims 26-31. In response, a person of ordinary skill in the art reading Baroody would readily recognize that maintaining stability of the composition is important and in order to do so, factors such as pH, viscosity, amounts of gelling agent etc., should be varied. Baroody recognizes the above factors as result effective variables and hence the application of the technique to stabilize the composition is not beyond the skill of an ordinary person, which according to the above KSR ruling would have been obvious. The reasonable expectation in this case is that varying the pH and gelling agents and viscosity results in variable stability of the composition.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1611

February 2, 2008


LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER